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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,810	09/20/2005	Vernon L. Alvarez	051530-5008-US	9490

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
08/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,810	ALVAREZ ET AL.	
	Examiner	Art Unit	
	DAVID LUKTON	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-49* is/are pending in the application.

4a) Of the above claim(s) *48 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *42-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Pursuant to the response filed 8/1/08, no claim has been added, cancelled, or amended. Claims 42-49 remain pending.

Applicants' election of Group 18 is acknowledged, i.e., a method of altering the course of a biochemical process (or any method that is properly subgeneric thereto), and with the proviso that methods of treating diseases are not included in this subgenus, and with the further proviso that diagnostic methods are also not included in this subgenus.

In addition, applicants' attempt to comply with the "election of species" requirement is acknowledged:

d) the elected cell type is any sort of cell that one might construe as cancerous;

e) the specific biochemical process to be altered is cell proliferation;

f) substituent variable X_1 is limited to Asp or Glu;

g) in the elected method, the polypeptide is contacted with the cells *in vivo*;

h) in the elected method, the polypeptide is administered intravenously.

In response to the requirement to elect a specific and fully defined polypeptide, applicants have chosen the following:

TDHQMARKS (SEQ ID NO:10)

However, this peptide does not fall within the scope of claim 42. Claim 42 requires that the subunit sequence contain **two** threonines (of which one is bonded to variable X_1).

The elected peptide contains just one. Accordingly, applicants are not fully responsive.

Applicants have traversed the restriction requirement by arguing that merely by paying the fee for a PCT application, applicants subsequently enjoy blanket "immunity" from restriction, no matter how many different inventions they have managed to group together into a single claim. Applicants, however, are not correct. Consider the following passage from the MPEP (section 1850):

> PCT Rule 13.2, as it was modified effective 01 July 1992, no longer specifies the combinations of categories of invention which are considered to have unity of invention. Those categories, which now appear as a part of Annex B to the Administrative Instructions, has been substituted with a statement describing the method for determining whether the requirement of unity of invention is satisfied.
>
> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.
>
> The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.
>
> Independent and Dependent Claims.
> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).
>
> If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.
>
> If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

As it happens, peptides of instant claim 42 were known prior to the filing date, and even prior to the priority date that applicants are attempting to claim (5/31/02). As noted in the specification (page 9, line 20), chlorotoxin was known prior to the priority date. Then there are journal articles such as J. A. DeBin (*Am J Physiol Cell Physiol* 264: 361-369, 1993) and patents such as Ullrich (USP 5905027) that describe methods of using chlorotoxin. Other peptides falling within the scope of claim 42 were also known before the priority date.

Nevertheless, applicants are invited to make the following admissions on the record:

a) all methods of using a peptide that comprises SEQ ID NO: 13 are obvious over all other methods of using a peptide that comprises SEQ ID NO: 13;

b) if a reference discloses one method of using a peptide that comprises SEQ ID NO: 13, that reference renders obvious all other methods of using a peptide that comprises SEQ ID NO: 13.

In the response to this Office action, it will become clear how much conviction underlies applicants' assertion that all methods encompassed by claim 42 are indistinct from one another.

Applicants have made the point that the claims do not exclude methods of treating humans or other organisms, and also do not exclude diagnostic methods. The examiner fully concurs. For the record, the instant claims (filed 1/24/08) absolutely **do** encompass methods of treating diseases in humans (and other organisms), and the claims also encompass diagnostic methods. But that was not the point made by the examiner in the previous Office action. The point was (and remains) that the **elected**

subgenus does not encompass methods of treating diseases in organisms, and the elected subgenus also does not encompass diagnostic methods. This is not to say, however, that rejoining of non-elected groups cannot or should not occur. For example, if it were to turn out that any method of inhibiting proliferation of cancer cells (for a given subgenus of peptides) were novel and otherwise allowable, it would be appropriate to rejoin claims drawn to a method of treating humans (or other mammals) afflicted with cancer.

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect species/ subgenera (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable (the lettering begins with "j"):

j) a specific type of cancer cell, such as a glioblastoma, or one of those recited in the passage spanning page 8, line 33 to page 9, line 10 of the specification;

k) one of the following: (i) in the elected method, cancer cell proliferation is to be inhibited; or (ii) in the elected method, cancer cell proliferation is to be augmented;

l) one of the following: (i) in the elected method, cancer cell proliferation is to be inhibited (or augmented) without the use of a second agent (which second agent does not comprise SEQ ID NO:13) or (ii) in the elected method, cancer cell proliferation is to be inhibited (or augmented) in combination with a second agent (which second agent does not comprise SEQ ID NO:13);

m) one of the following: (i) in the elected method, the "polypeptide" (referred to in line 2 of claim 42) contains 10 amino acids or fewer, or (ii) in the elected method, the "polypeptide" contains more than 10 amino acids;

n) a specific peptide **that falls within the scope of claim 42**, and which is consistent with the election of part "m" above.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. ›103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654